



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Clark R. Baker Jr.

Serial No.: 10/796,584

Filed: March 8, 2004

For: METHOD AND APPARATUS FOR
OPTICAL DETECTION OF MIXED
VENOUS AND ARTERIAL BLOOD
PULSATION IN TISSUE

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Group Art Unit: 3737

Confirmation No.: 1106

Examiner: Ramirez, John Fernando

Atty Docket: TYHC:0149/FLE/POW/COH
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October 22, 2007
Date


Toni Hill

PRE-APPEAL BRIEF REQUEST FOR REVIEW

With respect to the Final Office Action mailed on August 22, 2007, Appellant respectfully submits this Pre-Appeal Brief Request for Review. This Request is being filed concurrently with a Notice of Appeal.

Claim Rejections Under 35 U.S.C. § 112

In the Final Office Action, the Examiner rejected claims 1-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention. Appellant respectfully traverses these rejections in view of the clear legal and factual deficiencies discussed in detail below.

Legal Precedent

The essential inquiry pertaining to the definiteness requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. See M.P.E.P. § 2173.02. In reviewing a claim for compliance with 35 U.S.C. §

112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 U.S.P.Q.2d 1279, 1283 (Fed. Cir. 2000). As set forth in Section 2173 of the Manual of Patent Examining Procedure, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Deficiencies of the Rejections

In the Final Office Action, the Examiner stated that “it is unclear as to how one calculates and measures the phase difference between the two electromagnetic radiation signals.” Page 3. Embodiments of phase difference calculations are clearly described in the present application. For example, the phase difference may be calculated by determining the openness of a Lissajous plot of a red waveform versus an infrared waveform. Specification, para. 42-47. Further techniques for calculating the phase difference may include quantifying the cross-correlation function of the two waveforms as a function of a delay interval between them or subtracting the phases of the waveforms at a given frequency. Specification, para. 50. In view of these multiple exemplary techniques for measuring the phase difference between first and second electromagnetic signals described in the present application, Appellant respectfully asserts that independent claims 1 and 13 and their dependent claims clearly are not indefinite. Accordingly, Appellant respectfully asserts that the Examiner’s rejections under 35 U.S.C. § 112, second paragraph, are in error. Indeed, the Examiner clearly has not followed the guidelines set forth in Section 2173 of the M.P.E.P. in analyzing the definiteness of the present claim language.

Claim Rejections Under 35 U.S.C. § 103

The Examiner also rejected claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab et al. (U.S. App. Pub. No. 2003/0036689) in view of Swedlow et

al. (U.S. Patent No. 5,662,106). Of these rejected claims, claims 1 and 13 are independent. Appellant respectfully traverses these rejections in view of the clear legal and factual deficiencies discussed in detail below.

Legal Precedent

Regarding 35 U.S.C. § 103, the burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, *all* the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (emphasis added).

Deficiencies of the Rejections

The Examiner stated that venous blood is a strong absorber of light and “can represent a significant contributor to the total optical density during motion episodes.” Final Office Action, page 2. In pulse oximetry, a phenomenon known as “venous pulsation” may interfere with the calculation of various physiological parameters, such as oxygen saturation or pulse rate. Specification, para. 38. Venous pulsation is generally believed to be caused by venous blood backing up and pooling due to a lack of sufficient valves in the vascular anatomy. *Id.* Venous pulsation is more common in certain areas of the body where there are fewer valves, such as the head or forehead. *Id.* In addition, a patient’s medical condition may increase the likelihood that venous pulsation will occur. *Id.* Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. Specification, para. 39. Venous pulsation is distinguishable from motion artifact, in part, because it may occur *absent patient motion*. *See id.*

Accordingly, the present application is directed to detecting the presence of venous *pulsation* so that a caregiver may be notified and take measures to preclude the presence of further venous pulsations, e.g., by tightening the sensor on the patient. As such, independent claim 1 recites, *inter alia*, “detecting the presence or absence of venous pulsation ... and indicating the presence of venous pulsation to a caregiver if a venous pulsation is present.” Independent claim 13 recites, *inter alia*, “means for detecting the presence or absence of venous pulsation ... and means for indicating the presence of venous pulsation to a caregiver when venous pulsation is present.” Appellant does not dispute that motion artifacts can create

problems in measuring physiological parameters, such as oxygen saturation. However, this is *not the problem* addressed in the present application. On the contrary, the present application relates to detection and notification of *venous pulsation*, which is a *different phenomenon* from motion artifact.

In contrast, the Diab reference discloses a system where the venous *saturation* is quantified. Specifically, the Diab reference calculates an arterial saturation and a venous saturation. *See* Diab, para. 395. To measure the venous saturation, the Diab reference uses arterial saturation values, and the venous saturation measurement appears to derive from arterial saturation measurements. *See id.* The Diab reference explains:

In order to obtain the venous saturation, the minimum arterial saturation value, of points that exhibit non-zero value, is selected rather than the maximum arterial saturation value. The saturation can be provided to the display 336.

Diab, para. 395. Appellant finds no discussion in the Diab reference regarding specifically detecting the presence or absence of a venous *pulsation*. Furthermore, the Diab reference clearly does not disclose that an indication of venous pulsation is provided to a caregiver for any reason. Indeed, the Examiner stated, “Diab et al. do not disclose indicating the presence of venous pulsation to a caregiver if venous pulsation is present.” Final Office Action, page 4.

The Swedlow reference does not cure the deficiencies of the Diab reference. In the Final Office Action, the Examiner stated that “the Swedlow et al. patent teaches an indication of the presence of *venous pulsation* to a caregiver if *venous pulsation* is present.” *Id.* (emphasis added). However, the Examiner has completely misinterpreted the Swedlow reference, because *nothing* in the Swedlow reference discloses detection of *venous pulsation*, much less an indication of its presence. Rather, the Swedlow reference merely discloses a pulse oximeter that detects *motion artifacts*. *See* Abstract; col. 1, lines 10-13; col. 2, lines 52-53. That is, the Swedlow reference relates to detection of a motion artifact, “such as by the detector moving away from the skin temporarily.” Col. 2, lines 14-15. As discussed above, *motion artifacts are not venous pulsation*.

Equating motion artifacts with venous pulsation is clear error by the Examiner. Venous pulsations and motion artifacts are clearly *not the same*. Interference with pulse oximetry

readings may be caused by a wide variety of sources, such as, but not limited to, venous pulsation, physical movement of the patient, dysfunctional hemoglobin, low perfusion, intermittent pulsatility or arrhythmia, electromagnetic interference, ventilator-induced pressure changes, or ambient light. Each of these sources of interference is caused by *different* phenomena and may be handled *differently*. For example, as discussed above, and as addressed in the present application, *venous pulsation* is a phenomenon caused by a patient's vascular anatomy and aggravated by some medical conditions or procedures. *See* Specification, para. 38. A *motion artifact*, on the other hand, is due to movement of the sensor with respect to the patient. *See, e.g.,* Swedlow, col. 2, lines 11-15. Accordingly, despite the Examiner's attempt to equate venous pulsation with motion artifact, the cited references are deficient with respect to detecting and indicating the presence of *venous pulsation*.

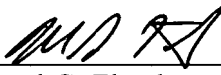
Appellant respectfully asserts that the Diab reference and the Swedlow reference, whether taken alone or in hypothetical combination, do not render obvious the present claims. Accordingly, Appellant respectfully asserts that the Examiner's rejections under 35 U.S.C. § 103(a) are in error.

Conclusion

In view of the foregoing, Appellant respectfully requests that the Panel reverse the Examiner's rejection of claims 1-22.

Respectfully submitted,

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